Individual Safety Report
3548973-3-00-01

McNeil Consumer Healthcare
McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

Page ____ of ____

Approved by FDA on 11/15/93
Mfr report #
UF/Distr report #
FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	or 5 yrs Date of birth:	(X) female ( ) male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr)
( ) life-threatening
( ) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
(X) other: none

3. Date of event (mo/day/yr): 5/1/00

4. Date of this report (mo/day/yr): 05/05/00

5. Describe event or problem

Consumer report of ACCIDENTAL OVERDOSE (ingestd an unknown amount) allegedly associated with one of our TYLENOL® acetaminophen Suspension products in her daughters. According to consumer, on 4/29/00, while the baby sitter was sleeping, her 4 year-old (Mfr report no 1357408a) and 5 year-old twin daughters ingested an unknown amount of product. The 4 year-old was taken to the emergency room and treated. The 5 year-old twins reportedly had AST and ALT levels taken on 5/1/00. One twin (Mfr report no 1358427a) reportedly had an AST of 127 and an ALT of 131. The other twin reportedly had an AST of 64 (SGOT INCREASED) and an ALT of 71. No symptms were reported in the children.

6. Relevant tests/laboratory data, including dates

5/1/00: AST and ALT were reportedly 64 and 71

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

no known conditions; NKDA

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Children's TYLENOL Suspension Product
#2

2. Dose, frequency & route used

#1 unknown amount, po
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 4/29/00; 1 day
#2

4. Diagnosis for use (indication)

#1 accidental ingestion
#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 Unknown
#2

7. Exp. date (if known)

#1 Unknown
#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

none

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-273-7303

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
(X) consumer
( ) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr): 05/05/00

5. (A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day ( ) 15-day
( ) 10-day (X) periodic
(X) initial ( ) follow-up #

8. Adverse event term(s)

OVERDOSE ACCID SGOT INCREASED
SGPT INCREASED

9. Mfr. report number

1358442A

E. Initial reporter

1. Name, address & phone #

AUG - 9 2000

2. Health professional? ( ) Yes ( ) No

3. Occupation

4. Initial reporter also sent report to FDA: ( ) Yes ( ) No ( ) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

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1